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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,538	02/03/2005	Kenji Sunagawa	KUP-6	7543
20808	7590	11/24/2009		
BROWN & MICHAELS, PC 400 M & T BANK BUILDING 118 NORTH TIOGA ST ITHACA, NY 14850			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT 3762	PAPER NUMBER
			NOTIFICATION DATE 11/24/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/523,538

Applicant(s)

SUNAGAWA, KENJI

Examiner

MICHAEL KAHLIN

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/226)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support on page 9 of the originally filed disclosure for an electrode or electrode coating on the cathode "to enzymatically enhance an oxygen reduction reaction." Although page 8 indicates that a catalyst is required, there does not seem to be support for the limitation that this catalyst is enzymatic or a coating on the cathode.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10, 11, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the cathode as a whole, cathode electrode, or the coating material formed on the surface of the cathode serves "to enzymatically enhance an oxygen reduction reaction." Additionally, it is unclear whether "enzymatically" requires that the coating actually contains an enzyme or merely

works in concert with the enzyme coating on the anode. The Examiner is considering the claim to require only that the coating work in concert with the anode "enzymatically."

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (US 3,943,936, hereinafter "Rasor") in view of Heller (US 6,294,281, hereinafter "Heller"). Rasor discloses the essential features of the claimed invention, including a pacemaker capable of implantation with the tip of a catheter and requiring no chest incision (Figs. 5A-5C and 9) having a control unit (30), a heart stimulating means (output of 30), an electrocardiograph information detecting means ("trigger input" and col. 11, lines 8-13), and a fuel cell power unit (col. 3, lines 19-21), wherein the control unit outputs the control signal based on the ECG information (col. 11, lines 8-13). Further, Rasor discloses that the control unit comprises a stimulation timing determining means ("pulse forming circuit") that decides the timing of pulses and a stimulation timing changing means (col. 11, lines 15-18) that changes the timing of stimulation when certain conditions are met. Rasor does not disclose that the fuel cell is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a

biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions to enzymatically enhance an oxygen reduction reaction; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid without the need for a container to contain the electrolyte solution or metabolic product; and wherein the anode and cathode contact the electrolyte solution. Heller teaches a biological fuel cell for use with implantable devices (col. 2, lines 60-67) that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators (redox polymer layer; cols. 5-9) and oxidative enzymes for biological fuels (cols. 9-12), wherein the layer prevents oxygen existing in a biological body from contacting the anode (col. 8, line 16; "poly(acrylic acid)"), and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions to enzymatically enhance an oxygen reduction reaction (col. 13, lines 21-47 and col. 14, lines 4-18 - the reaction is "enzymatically enhanced" by the enzymes on the anode); wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid without the need for a container to contain the electrolyte solution or metabolic product (col. 14, lines 35-43 and Fig. 1); and wherein the anode and cathode contact the electrolyte solution (col. 14, lines 35-43) to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rasor's invention by providing a biological fuel cell for use with implantable devices that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid; and wherein the anode and cathode contact the electrolyte solution to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Please note that Heller's coating material (poly(acrylic) acid) inherently prevents oxygen existing in a biological body from contacting the anode. See Reichert et al. (US 5,270,128; col. 3, lines 40-65) as evidence of inherency. In the alternative, it is notorious in the fuel cell arts to prevent oxygen from contacting anodes to provide the predictable result of avoiding degradation of the anode material. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by preventing oxygen from contacting the anode to provide the predictable result of avoiding degradation of the anode material.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor in view of Heller and Fujii et al. (US 5,411,535, hereinafter "Fujii"). Rasor's

modified invention (as applied to claim 10) discloses the essential features of the claimed invention except for a transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit. Fujii teaches an implantable pacemaker, similar to the one taught by Rasor, with transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit (Fig. 7) to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by providing transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body.

Response to Arguments

8. Applicant's arguments filed 9/1/2009 have been fully considered but they are not persuasive. Applicant argued that Rasor fails to disclose the insertion and/or removal of an ultra miniature pacemaker without a chest incision that does not require surgery or intravenous or transarterial insertion. However, these limitations are not claimed, and Rasor clearly shows the implantation of the device via catheter in Figures 5A-5C.
9. Applicant further argued that Rasor fails to disclose a biological chemical power source, but that the power source disclosed by Rasor is a pressure-based mechanical

power system. However, Rasor explicitly indicates at column 3, line 20 that the power sources can be "fuel cells."

10. Applicant further argued that Heller discloses several embodiments that comprises toxic substances and provided information regarding their toxic effects, and further argued that, although disclosed by Heller as being bound to a polymer coating, polymers have been known to lose their structural integrity. However, the Examiner respectfully asserts that, regardless of hypothetical possibilities of future complications, Heller clearly and explicitly indicates that the inventive system is implantable in a living human body at column 14, lines 33-43, and thus maintains that Heller's teaching is applicable to Rasor's system.

11. Applicant further argued that Reichert's disclosed invention requires a collector for undesirable metabolic by-products. However, Reichert was not relied upon as a modifying reference, but merely as evidence for an inherent feature of Heller's poly(acrylic) acid coating. There is no proposed modification, and thus there can be no "teaching away" from making the modification. Heller discloses the absence of the need for a collector at column 14, lines 33-34 and Figure 1 where the fuel and waste products are carried by the blood flowing through the device.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Michael Kahelin/
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